GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:545
ANSWERED ON:04.05.2005
SALE OF BANNED DRUGS
Satheedevi Smt. P.

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government is aware that many medicines which are banned in developed countries are widely being sold in the country;

(b) if so, the measures being taken by the Government to check the supply of such medicines;

(c) the details of the recommendations of Hathi Commission report in this regard; and

(d) the steps taken/being taken by the Government to implement the said recommendations?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS)

(a)to(d): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 545 FOR 4TH MAY, 2005

There is no system of global banning of drugs. Certain drugs and formulations withdrawn in one or some countries may continue to be marketed in other countries. The decision to ban a drug by the regularity authorities, is normally based on a risk assessment process, which is influenced by a number of factors such as disease pattern in a country, indications and dosages of the drug permitted, varying reactions of certain ethics groups in a given population, availability of safer substitutes and overall safety profile of the drug. It is well known fact that administration of any drug is not absolutely free from side effects or adverse reactions in a statistically insignificant minority of the population.

There is an adequate mechanism in India to review the status of the drug formulations as and when any serious adverse event is reported in the International journals, WHO Newsletters or when a drug formulation is reported to have been withdrawn in some countries. The use of the drug so reported is assessed in consultation with the experts based on available technical information, benefit-risk ratio, local needs etc. The matter is further considered by the Drugs Technical Advisory Board (DTAB), a statutory body under the Drugs & Cosmetics Act, 1940.

Seventy six categories of drug formulations have so far been prohibited in the country by the Central Government, which were considered irrational or harmful in the context of present knowledge. In the recent past, drugs like Astemizole, Terfinadine, and Rofecoxib have been prohibited after due assessment of their benefit-risk ratio by the experts, while drugs like Analgin, Hydroxyquinoline, Furazolidone, Phenylpropanolamine, Nimesulide etc. have been permitted to be continued to be marketed after due examination of their safety and use in the country.

A National Pharma-co-vigilance Programme has been launched in 2004 to capture data on adverse reactions to drug use in the country.

The Committee on Drugs and Pharmaceuticals Industry under the Chairmansip of Shri Jaisukhlal Hathi was constituted on 8th February, 1974, by the Ministry of Chemicals and Fertilizers to examine various facts of the Drug Industry in India with a view to promoting growth of the Drug Industry and was not related to sale of banned drugs.

However, a high level committee was constituted by the Government of India in the Ministry of Health & Family Welfare in the year 2001, under the Chairmanship of Director General of Health Services to undertake detailed examination of the issue of alleged marketing of internationally banned drugs in India. The Committee in its report submitted in May, 2002, expressed the view that there is adequate mechanism in the country to examine and prohibit sale of drugs, which have been prohibited in some countries. The apprehension that internationally banned drugs continued to be marketed in the country is not based on facts.